

# Rapid Data Analysis – Systemic fluoroquinolones and thrombotic thrombocytopenic purpura (TTP)

**First published:** 25/08/2021

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS42641

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### Study ID

42642

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### DARWIN EU® study

No

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### Study countries



Germany



United Kingdom

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### Study description

Fluoroquinolone antibiotics (of which ciprofloxacin is an example) are widely used for the treatment of certain types of microbial infection. Recently, their use has been reported as being associated with the onset of Thrombotic Thrombocytopenic Purpura (TTP), a rare but potentially fatal disease that causes blood clots to form in small blood vessels throughout the body. This issue is being evaluated by the European Union's Pharmacovigilance Risk Assessment Committee (PRAC), a regulatory body responsible for assessing and monitoring the safety of human medicines. This study simply describes how often TTP occurs after patients are prescribed fluoroquinolones. To allow contextualisation of the results, the same analysis has been done in two other groups of patients prescribed other antibiotic medicines. The first group are patients prescribed broad spectrum penicillins. The second group are patients who have been prescribed azithromycin. The results of this study will be used by the PRAC in its decision-making process by helping to decide if regulatory action needs to be taken to protect patients taking fluoroquinolones.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[European Medicines Agency \(EMA\)](#)

**First published:** 01/02/2024

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**Institution**

# Contact details

## Study institution contact

EMA EMA ICU@ema.europa.eu

Study contact

[ICU@ema.europa.eu](mailto:ICU@ema.europa.eu)

## Primary lead investigator

EMA EMA

Primary lead investigator

# Study timelines

## Date when funding contract was signed

Planned: 01/06/2021

Actual: 01/06/2021

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## Study start date

Planned: 01/06/2021

Actual: 01/06/2021

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## Date of final study report

Planned: 25/08/2021

Actual: 25/08/2021

# Sources of funding

- EMA

# Study protocol

[Analysis-Plan\\_fluoroquinolones\\_TTP.pdf](#) (497.61 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Is there evidence of an association between systemic fluoroquinolones and acquired TTP? (i.e. is there an increased frequency of acquired TTP following treatment with fluoroquinolones?)

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J01MB) Other quinolones

Other quinolones

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**Medical condition to be studied**

Thrombotic thrombocytopenic purpura

## Population studied

**Short description of the study population**

Patients with a first prescription for either a systemic fluoroquinolone or a systemic broad-spectrum penicillin (or azithromycin). Only the first prescription

date for either of the two types of antibiotics was considered. Patients with a concomitant first prescription for both a systemic fluoroquinolone and a systemic broad-spectrum penicillin (or azithromycin), and patients with a history of TTP were excluded.

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### **Age groups**

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

10000

## Study design details

### **Data analysis plan**

The incidence rate of TTP was calculated from the number of patients with TTP during the follow-up period and the total follow-up time in years of follow-up in each of the two treatment groups. The 95% confidence intervals for the incidence rates were calculated.

## Documents

## Study results

[Final\\_report\\_fluoroquinolones\\_TTP 20210824.pdf](#) (848.55 KB)

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## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s)

THIN® (The Health Improvement Network®)

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### Data source(s), other

THIN, IQVIA Disease Analyzer Germany

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No